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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|-----------------|-------------|----------------------|---------------------|------------------|
| 09/770,875      | 01/26/2001  | Witold Cieplak       | 2026-4253US7        | 15609            |

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BUGAISKY, GABRIELE E

[REDACTED] ART UNIT [REDACTED] PAPER NUMBER

1653

DATE MAILED: 07/01/2003

(R)

Please find below and/or attached an Office communication concerning this application or proceeding.

|                              |                                  |                  |
|------------------------------|----------------------------------|------------------|
| <b>Office Action Summary</b> | Application N .                  | Applicant(s)     |
|                              | 09/770,875                       | CIEPLAK, WITOLD  |
|                              | Examiner<br>Gabriele E. BUGAISKY | Art Unit<br>1653 |

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

#### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

#### Status

- 1) Responsive to communication(s) filed on 25 March 2003.
- 2a) This action is FINAL.                  2b) This action is non-final.
- 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

#### Disposition of Claims

- 4) Claim(s) 5 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) Claim(s) \_\_\_\_\_ is/are allowed.
- 6) Claim(s) 5 is/are rejected.
- 7) Claim(s) \_\_\_\_\_ is/are objected to.
- 8) Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

#### Application Papers

- 9) The specification is objected to by the Examiner.
- 10) The drawing(s) filed on \_\_\_\_\_ is/are: a) accepted or b) objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

- 11) The proposed drawing correction filed on \_\_\_\_\_ is: a) approved b) disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) The oath or declaration is objected to by the Examiner.

#### Priority under 35 U.S.C. §§ 119 and 120

- 13) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) All b) Some \* c) None of:
1. Certified copies of the priority documents have been received.
  2. Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.
- 14) Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) The translation of the foreign language provisional application has been received.
- 15) Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

#### Attachment(s)

- 1) Notice of References Cited (PTO-892)
- 2) Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) Information Disclosure Statement(s) (PTO-1449) Paper No(s) \_\_\_\_\_.
- 4) Interview Summary (PTO-413) Paper No(s). \_\_\_\_\_.
- 5) Notice of Informal Patent Application (PTO-152)
- 6) Other: \_\_\_\_\_.

## **DETAILED ACTION**

The amendment of 3/2003 is acknowledged. Claims 5 remains under consideration.

### ***Priority***

The priority matter has been corrected. Priority is granted to 07/311,612 (2/15/1989). In response to Applicants' comments in the petition under 37C.F.R. 1.182 in 07/311,612 regarding confusion about the Examiner's granting of priority in earlier application 07/542149 (exhibit A), the MPEP has been undergone major revision since 1994 to reflect the great changes in patent procedure that have occurred; unfortunately, the simple manner in which inventorship could be corrected then is no longer an option.

### ***Specification***

The disclosure remains objected to because of the following informalities: Table 2 (pages 16 and 16a) is a photocopy of a sequence with extremely small, nearly illegible font (many of the "G"s are indistinguishable from the "C"s. It is highly unlikely that a good image could be generated for publication from this table. Applicant is requested to provide a more legible copy of this information.

Appropriate correction is required.

Applicant states that "enclosed herewith are substitute pages 16, 16a, 16b, and 16c"; while these pages may be enclosed in the large submission, the location of the substitute pages has not been identified.

***Claim Rejections - 35 USC § 112***

The rejection of claim 5 under 35 U.S.C. 112, second paragraph, as being indefinite, is withdrawn, based upon the amendment.

***Claim Rejections - 35 USC § 102***

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

- (a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.
- (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.
- (e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371(c) of this title before the invention thereof by the applicant for patent.

The changes made to 35 U.S.C. 102(e) by the American Inventors Protection Act of 1999 (AIPA) and the Intellectual Property and High Technology Technical Amendments Act of 2002 do not apply when the reference is a U.S. patent resulting directly or indirectly from an international application filed before November 29, 2000. Therefore, the prior art date of the reference is determined under 35 U.S.C. 102(e) prior to the amendment by the AIPA (pre-AIPA 35 U.S.C. 102(e)).

The rejection of claim 5 under 35 U.S.C. 102(b) as being anticipated by BURNETTE *et al.* (Science) is withdrawn, as Applicant now has priority to 07/311,612 (2/15/1989). The

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declaration filed on 3/25/2003 under 37 CFR 1.131 has been considered and precludes rejection under 35U.S.C.§102(a) by this reference.

Claim 5 remains rejected under 35 U.S.C. 102(e) as being anticipated by W. N.BURNETTE (US patent 5773600). The reference is anticipatory for the claimed subject matter because it provides protein expressed from a mutated gene encoding an S1 subunit of pertussis toxin comprising a substitution at arg9 to lys9 (see e.g., column 16, lines 6-45.) The instant method of using the DNA is not deemed patentably distinct from the patented DNA of the claims.

The declaration filed on 3/25/2003 under 37 CFR 1.131 has been considered but is ineffective to overcome the W. N.BURNETTE patent . The Burnette reference is a U.S. patent or U.S. patent application publication of a pending or patented application that claims an invention not patentably distinct from the rejected invention. An affidavit or declaration is inappropriate under 37 CFR 1.131(a) when the reference is claiming the same patentable invention, see MPEP § 2306. If the reference and this application are not commonly owned, the reference can only be overcome by establishing priority of invention through interference proceedings. See MPEP Chapter 2300 for information on initiating interference proceedings. If the reference and this application are commonly owned, the patent may be disqualified as prior art by an affidavit or declaration under 37 CFR 1.130. See MPEP § 718.

*Claim Rejections - 35 USC § 103*

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The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claim 5 remain rejected under 35 U.S.C. 103(a) as being unpatentable over PIZZA *et al.* (US patent 5925546), for reasons of record,. The reference provides for recombinant production of a pertussis S1 subunit with a mutation at Arg9 and Tyr8; thus, the mutated subunit of the reference comprises a mutation at Arg9. The reference does not specifically teach the R>K substitution, but does suggest (see e.g., column 2, lines 47-67) the substitution with any amino acid that differs from the one to be mutated. It would have been obvious to one of ordinary skill in the art at the time of the invention, to utilize any amino acid, including lysine, to substitute for the Arg9 of the S1 subunit of pertussis, and to subsequently recombinant produce a subunit of altered toxicity without altering the immunologic properties. Amendment to recite a single site substitution at arg 9 could overcome this rejection.

Applicant's arguments filed 3/2003 have been fully considered but they are not persuasive. It is stated that the amended claims now recite a single amino acid mutation. The Examiner disagrees. The claimed method makes a polypeptide which comprises a mutation at position 9; this cannot be construed to be limited to a single amino acid substitution.

Further the declaration filed on 4/9/2003 under 37 CFR 1.131 has been considered but is ineffective to overcome the Pizza *et al.* patent. The Pizza reference is a U.S. patent or U.S. patent application publication of a pending or patented application that claims the rejected invention. An affidavit or declaration is inappropriate under 37 CFR 1.131(a) when the

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reference is claiming the same patentable invention, see MPEP § 2306. If the reference and this application are not commonly owned, the reference can only be overcome by establishing priority of invention through interference proceedings. See MPEP Chapter 2300 for information on initiating interference proceedings. If the reference and this application are commonly owned, the patent may be disqualified as prior art by an affidavit or declaration under 37 CFR 1.130. See MPEP § 718.

### ***Double Patenting***

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claim 5 remains provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 11, 13 and 15-16 of copending Application No. 07/542149. Although the conflicting claims are not identical, they are not patentably distinct from each other because it is obvious to use a transformed cell containing a plasmid encoding a specific protein in a method of making that protein. In general, a method of making a protein by recombinant means is not deemed patentably distinct from the isolated DNA, plasmid, and transformed host cells.

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This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

It is noted that Applicants response traverses this provisional rejection and states that the advisability of filing of a terminal disclaimer will be considered should the claims of the 07 application be allowed and issue.

***Conclusion***

**THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

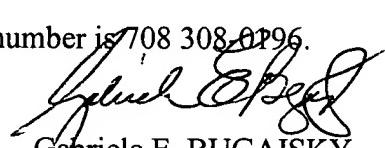
A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Gabriele E. BUGAISKY whose telephone number is (703)308-4201. The examiner can normally be reached on 8:15 AM- 2 PM, Tu & Th, 8:15 AM-1:30 PM, We & Fr.

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If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Christopher SF Low can be reached on (703) 308-2923. The fax phone numbers for the organization where this application or proceeding is assigned are 703 308-4242 for regular communications and 703 308-4242 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 708 308-0296.



Gabriele E. BUGAISKY  
Primary Examiner  
Art Unit 1653

June 29, 2003